

From: [Jay Field](#)
To: [Robert Gensemer](#)
Cc: [Eric Blischke/R10/USEPA/US@EPA](#); [Benjamin Shorr](#); [Burt Shephard/R10/USEPA/US@EPA](#); [Chip Humphrey/R10/USEPA/US@EPA](#); [Joe Goulet/R10/USEPA/US@EPA](#); [Robert Neely](#)
Subject: Re: Bioassay Interpretation at Portland Harbor
Date: 06/15/2009 11:24 AM

I do not see anything in MacDonald and Landrum about how to deal with statistical significance once the reference envelope is established. If we're talking about samples that would be classified as Level 1, I could see some rationale for considering them as Level 1- for samples that are Level 2 or greater (>20% difference from 95th percentile of the reference envelope), those are likely low-power results and should retain their classification. FYI, according to my calculations, there are 24, 7, and 1 non-significant samples for Levels 1,2,&3 respectively.

Jay

Robert Gensemer wrote:

Eric: That is my understanding as well. The 2008 MacDonald and Landrum report is pretty clear about this too, and further points out the need for the test of statistical significance (and the RE approach in general) to be conducted separately and independently for each of the four bioassay endpoints.
-Bob

-----Original Message-----

From: Blischke.Eric@epamail.epa.gov
[<mailto:Blischke.Eric@epamail.epa.gov>]
Sent: Monday, June 15, 2009 9:35 AM
To: Jay Field
Cc: Benjamin Shorr; Shephard.Burt@epamail.epa.gov;
Humphrey.Chip@epamail.epa.gov; Goulet.Joe@epamail.epa.gov; Robert Gensemer; Robert Neely
Subject: Re: Bioassay Interpretation at Portland Harbor

I agree that statistical significance was not part of the reference envelope approach but I thought that statistical significance needed to be taken into account in the comparison to negative control.

Eric

Jay Field
[<Jay.Field@noaa.gov>](mailto:Jay.Field@noaa.gov)

To	Eric
Blischke/R10/USEPA/US@EPA	
06/12/2009 04:15	
cc	
PM	Burt
Shephard/R10/USEPA/US@EPA,	Chip
Humphrey/R10/USEPA/US@EPA,	Joe Goulet/R10/USEPA/US@EPA,
	rgensemer@parametrix.com ,
Robert	Neely
<Robert.Neely@noaa.gov> ,	Benjamin Shorr
	<Benjamin.Shorr@noaa.gov>
Subject	

at

Re: Bioassay Interpretation
Portland Harbor

Eric,
Attached is a spreadsheet that shows the data we have for the 293
tox samples and the calculated effect levels, which were based on
the values

for the 4 endpoints in table RE-2. As previously mentioned, we did
not take into account statistical significance, since it was our
understanding that statistical comparisons are not part of the
reference

envelope approach as described by MacDonald & Landrum.

Have we received any of the information that you requested from
John Toll and LWG?

Have a good weekend,

Jay

Blischke.Eric@epamail.epa.gov wrote:

All, I had another voicemail exchange with John, he
would like to have
this discussion next Tuesday, June 16th. Does that
work? I will
continue to work on getting some information ahead of
time.

Eric

Burt

Shephard/R10/USE

PA/US

To

Blischke/R10/USEPA/US@EPA

Eric

06/08/2009 11:44

cc

AM
Humphrey/R10/USEPA/US@EPA,

Chip

jay.field@noaa.gov, Joe

Goulet/R10/USEPA/US@EPA,

rgensemer@parametrix.com

Subject

Interpretation at

Re: Bioassay

Harbor(Document link:

Portland

Eric Blischke)

Eric,

I think Jay's suggestion is a good one, we need to know exactly what

LWG

has done before we can identify the discrepancies. For now, we don't know what they've done that differs from us. I also think we should bring Don MacDonald into the discussions with LWG.

Surprisingly given my schedule since January, I'm actually in the

office

all week this week, although most of Wednesday is tied up with Upper Columbia River site meetings.

Best regards,

Burt Shephard
Risk Evaluation Unit
Office of Environmental Assessment (OEA-095) U.S.
Environmental
Protection Agency, Region 10 1200 6th Avenue Seattle, WA
98101

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"If your experiment needs statistics to analyze the results, then you ought to have done a better experiment"

- Ernest Rutherford

Eric

Blischke/R10/USE

PA/US

To

Burt

Shephard/R10/USEPA/US@EPA,

06/08/2009 10:35
rgensemer@parametrix.com, Joe

AM
Goulet/R10/USEPA/US@EPA,

jay.field@noaa.gov

cc

Humphrey/R10/USEPA/US@EPA

Chip

Subject

Interpretation at

Bioassay

Portland Harbor

At the AOPC meeting, it became apparent that our interpretation of the sediment bioassay results did not match the LWG's interpretation. I

am

interested in understanding the basis for this discrepancy. Based on

my

review of the data, the bioassay results match up with the bins that

we

established in Table RE-2 in our March 31, 2009 direction to LWG (see previous email). Last week, I put in a call to John Toll to try to understand the LWG's interpretation. Although I did not speak

directly

with John, he left me a voice mail that described 3 possibilities for the discrepancy:

- 1) The raw response rates differ slightly - e.g., 15% vs. 17%. John does not know why this is the case.
- 2) Significance Testing. The LWG used the biostats software. He indicated that this is a complicated procedure but that the LWG

followed

the decision tree associated with the software package and did not

make

- any choices that were inconsistent with the decision tree.
- 3) The calculation of the level of the hit (e.g., low, moderate or severe toxicity) based on a comparison to the reference envelope was based on an added 10% to the reference envelop opposed to multiplying

by

the reference envelope value by 1.1 or 1.2.

I would like to set up a time to discuss this sometime this week. Please let me know when you might be available. I will work with John to hopefully have some information that we can use to focus the discussion.

Thanks, Eric,

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Jay Field
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(See attached file: PH_ToxRef_090612.xls)

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